PHILIPS

K120255

510(k) Summary (21 CFR 807.92)

APR 19 2012

A. SUBMITTER INFORMATION

Submitter's name	Philips Digital Mammography Sweden AB
Address	Smidesvägen 5 SE-171 41 Solna Sweden
Establishment registration number	3009307584
Contact person	Gustav Lins
Telephone	+46-8-623 52 00
FAX	+46-8-623 52 01
Title	Manager Regulatory Affairs
Date of the summary preparation	2012-01-24

B. DEVICE IDENTIFICATION

Device trade name	Philips MicroDose L30
Device common name	Full-Field Digital Mammography X-ray System
Classification name	Full-Field Digital Mammography X-ray System
Classification product code	MUE
Device class	II
Regulation code	21 CFR 892.1715

C. DEVICE DESCRIPTION

The Philips MicroDose L30 is a full-field digital mammography system comprised of an image acquisition system, a gantry and an acquisition workstation computer equipped with a keyboard, a keypad, a mouse, and a monitor. The image acquisition system includes a digital detector of photon counting technology, x-ray tube (with tungsten target and aluminum filtration), high voltage generator, compression paddle(s), and multi-slit collimator. The acquisition workstation is the user interface for preparing and initiating image acquisition, image processing, and image transfer to the desired destination (e.g. PACS) for diagnosis and archiving.

The Philips MicroDose L30 detector is based on photon counting technology and consists of a large number of crystalline silicon strip detectors. The technology enables high detection efficiency of photons and efficient rejection of electronic noise. The Philips MicroDose L30 uses a multi-slit scanning technique that prevents image degradation caused by scattered radiation by removing photons scattered in the breast and not directed towards the detector. These factors combine into a dose efficient system.

The Philips MicroDose L30 provides three exposure modes; manual, automatic (parameters predefined based on compressed breast thickness), and SmartAEC. SmartAEC continuously adjusts the exposure based on measured transmission from the leading detector edge.

PHILIPS

D. INDICATIONS FOR USE

The Philips MicroDose L30 is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The Philips MicroDose L30 is intended to be used in the same clinical applications as traditional film/screen systems.

E. PREDICATE DEVICE

	Predicate device
Device Classification Name	Full Field Digital, System, X-ray, Mammographic
510(k) Number	K110025
Device Name	Sectra MicroDose Mammography
Model	L30
Applicant	Sectra Imtec AB
Product Code	MUE
Advisory Committee	Radiology

F. TECHNICAL CHARACTERISTICS

As described in K110025, the Philips MicroDose L30 System employs photon counting technology; x-ray photons are captured in the detector and ultimately converted to an electrical signal, forming a digital image. All system components, hardware, and system features of the subject device are identical to the predicate MicroDose System. This 510(k) premarket notification is to obtain FDA clearance for the quantitative reduced dose claim for the MicroDose system based on the supporting clinical data. There is no change in the indications for use of the MicroDose system. The principle of operations of the MicroDose system is not affected, since there is no change to the device including image acquisition, X-ray generation, user interface, etc.

As described in the original 510(k), K110025, performance data from non-clinical testing of the Sectra MicroDose Mammography L30 covering Sensitometric response, Spatial resolution, Noise analysis, Signal-to-noise-ratio transfer – DQE, Dynamic range, Automatic exposure control performance, Phantom testing, Patient radiation dose was compared with data from the predicate devices. This comparison showed that the Sectra MicroDose Mammography L30 device performed as well as or better than the predicate devices in all relevant areas. The testing was performed in accordance with generally accepted test methods, e.g. using IEC standards, published factors for dose calculations etc. In addition, clinical evidence including published studies on various national mammography screening programs demonstrated consistent levels of dose reduction with the use of the MicroDose system compared to other FFDM and film screen systems.

G. CONCLUSION

The Philips MicroDose L30 described in this submission is substantially equivalent to the predicate device in indication for use, principle of operation, technology and materials. Performance data demonstrate that the devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Gustav Lins
Manager Regulatory Affairs
Philips Digital Mammography Sweden AB
Smidesvagen 5
SE-171 41 SOLNA
SWEDEN

APR 19 2012

Re: K120255
Trade/Device Name: Philips MicroDose L30
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: January 24, 2012
Received: January 27, 2012

Dear Mr. Lins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120255

Device Name: Philips MicroDose L30

Indications for Use: The Philips MicroDose L30 is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer.
The Philips MicroDose L30 is intended to be used in the same clinical applications as traditional film/screen systems.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120255

Page _1_ of _1_